

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

LARA OCHOA, José Manuel
Francisco

Appl. No.: 10/502,403

§ 371(c) Date: June 20, 2005

For: **Pharmaceutical Composition to
Control Blood Glucose in
Patients with Type 2 Diabetes**

Confirmation No.: 3497

Art Unit: 1611

Examiner: Rae, Charlesworth E.

Atty. Docket: 2099.0090000/PAJ/LMB

**Information Disclosure Statement
Under 37 C.F.R. § 1.97(c)**

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on the accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the patentability of this application as defined in 37 C.F.R. § 1.56, and in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.97 and 1.98.

Copies of documents **FP1** to **FP5** and **NPL1** to **NPL27** are submitted. However, copies of U.S. patents and patent application publications cited on the attached Form PTO/SB/08A, documents **US1** to **US13**, are not submitted in accordance with 37 C.F.R. § 1.98(a)(2).

In accordance with 37 C.F.R. § 1.98(a)(3), Applicant's undersigned representative submits the following discussion of the relevance of the non-English language documents **FP2**, **FP4** and **NPL11** cited on Form PTO/SB/08B:

Document **FP2**, WO 00/40233 A1, is in the German language. The document FP2 was cited in a search report by a foreign patent office in related International Application No. PCT/MX02/00003. Submission of an English language version of the search report, document **NPL25**, that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of relevance. *See* 1138 Official Gazette 37, 38. In addition, an English language abstract of document FP2 can be found on the face page of the reference.

Document **FP4**, WO 03/061643 A1, is in the Spanish language. An English language abstract of document FP4 can be found on the face page of the reference.

Document **NPL11**, González-Ortiz, M., *et al.*, "Eficacia y seguridad de la terapia hipoglucemiante oral combinada de glimepirida más metformina en una sola forma farmacéutica en pacientes con diabetes mellitus tipo 2 y falla secundaria a monoterapia con glibenclamida," *Rev. Invest. Clin.* 56: 327-333 (May-June 2004), is in the Spanish language. An English language translation of document NPL11 is attached as document **NPL12**.

The Examiner's attention is directed to the following co-pending U.S. Patent Application, which is directed to related technical subject matter:

Application No. 11/517,567, inventors Regalado, A.S., *et al.*, filed September 8, 2006; published on November 15, 2007 as U.S. Patent Publication No. 2007/0264331 A1 and cited herewith as document **US13**.

The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an

action that otherwise closes prosecution in the application. Attached is our Online Credit Card Payment Authorization in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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Date: 08/24/2009

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